

**SUMMARY OF SAFETY AND EFFECTIVENESS**  
**510(k) Summary**

**INDEFLATOR 20/30™ Inflation Device and 20/30 PRIORITY PACK™**

**Device Name:** INDEFLATOR 20/30™ Inflation Device  
20/30 PRIORITY PACK™ Accessory Kit

**Devices to which Equivalence is Claimed:** ACS INDEFLATOR 20/20™ (K872981, October 20, 1987 and Baxter Inflation Pro™ II inflation device (K895836, December 20, 1989).

**Indication for Use:**

**INDEFLATOR 20/30™ Inflation Device-** The INDEFLATOR 20/30™ Inflation Device is recommended for use during cardiovascular procedures in conjunction with interventional devices such as balloon catheters to create and monitor pressure in the balloon catheter.

**20/30 PRIORITY PACK™ Accessory Kit-** The Accessory Kit is recommended for use during cardiovascular procedures in conjunction with interventional and/or diagnostic devices (e.g., balloon dilatation catheters, arterectomy devices, stent delivery systems, intravascular ultrasound devices.)

**Device Description:**

The INDEFLATOR 20/30™ Inflation Device is a manually operated device used to pressurize and depressurize balloon catheters. Pressure can be monitored via a pressure gauge.

The 20/30 PRIORITY PACK™ is comprised of the INDEFLATOR 20/30™ inflation device packaged with accessories used during vascular procedures in conjunction with interventional or diagnostic devices. These accessories include a torque device, a guide wire introducer and a rotating hemostatic valve.

**SUMMARY OF SAFETY AND EFFECTIVENESS (continued)**

**Summary of Substantial Equivalence:** The indications, methods and conditions of use, packaging process and location, sterilization process and location are similar to those of the currently marketed ACS INDEFLATOR 20/20™ Inflation Device. The 20/30 PRIORITY PACK™ includes accessories that have been previously cleared and the INDEFLATOR 20/30™ Inflation device, which is similar to the ACS INDEFLATOR 20/20™ Inflation device. The indications for use are similar to the Baxter Edwards Inflation Pro™ II.

The INDEFLATOR 20/30™ Inflation Device is similar in design and indicated use to the predicate devices.

**Conclusion:** The INDEFLATOR 20/30™ Inflation Device is substantially equivalent to the currently marketed ACS INDEFLATOR 20/20™ and the Baxter Edwards Inflation Pro™ II.